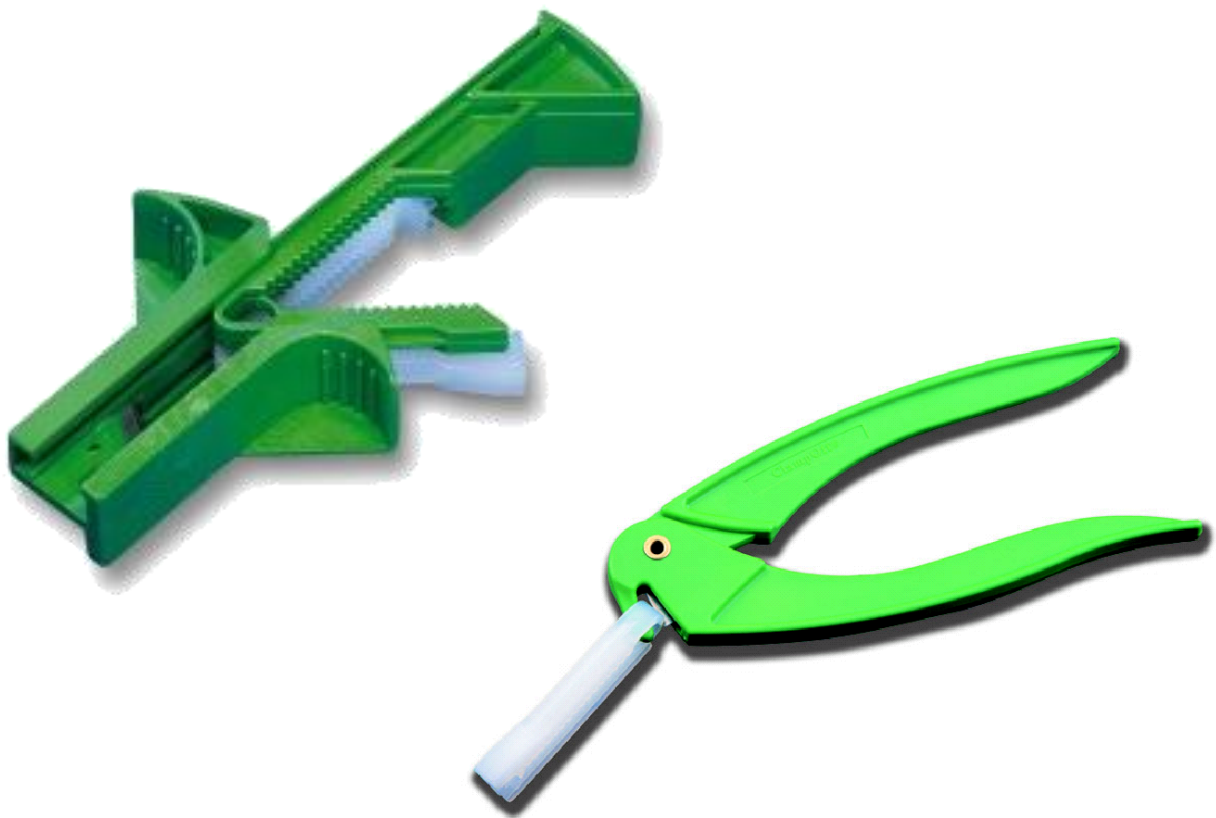




ClampCut® and ClampOff® User's Manual





Purpose

The purpose of this manual is to describe how **ClampCut®** and **ClampOff®** should be used. **ClampCut®** is a disposable device used to clamp and cut the umbilical cord of a newborn baby. Later, **ClampOff®** can be used to remove the clamp again.

The manual has been designed for Certified Users and Trained Users and contains:

- Price Invena's Certification Policy.
- a step-by-step procedure for using **ClampCut®** and **ClampOff®**.
- a list of frequently asked questions and corresponding answers

Certification Policy

To ensure that all users of **ClampCut®** apply the product correctly, Price Invena enforces a certification policy, which is described below.

As described in the box to the left, there are 3 user-levels, each of which has different degrees of training. The following is a list of rules regarding the use of **ClampCut®**.

Certified Instructor (CI) – has been trained by Price Invena to sell **ClampCut®** and to train and certify Certified Users.

Certified User (CU) – has completed the **ClampCut®** Training, can purchase and apply **ClampCut®** and can train staff to become a Trained User.

Trained User (TU) – has been trained by a CU and is allowed to apply **ClampCut®**

If you are a Certified User (CU):

- You can train other hospital staff to become Trained Users (TU).
- You are responsible for keeping a logbook of the TUs you have trained (Logbooks are provided by your sales representative).
- You are allowed to apply and purchase **ClampCut®**.
- You must have a certificate with your name, date of issue, issuing party and name of your hospital. The certificate is personal and cannot be handed over to a third party. The certificate must be renewed every 12 months.

If you are a Trained User (TU):

- You can apply **ClampCut®**.

How to apply **ClampCut®**

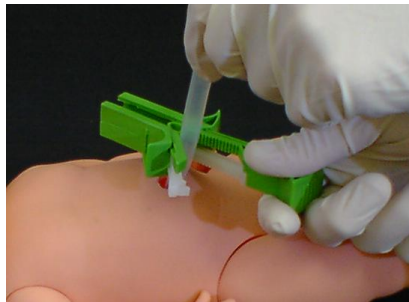
The following is a step-by-step procedure describing how to apply **ClampCut®**.



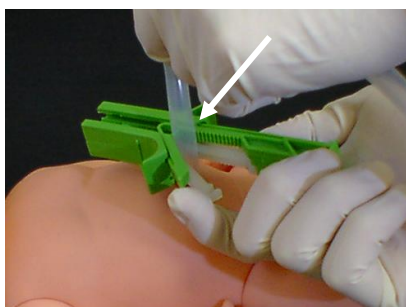
ClampCut's® components

1. **ClampCut®** consists of two components, the white clamp and green slider & housing.
2. **ClampCut®** can be applied using the correct-grip, both of which are demonstrated in the pictures below.
3. After the clamp has been applied, it is possible to count the 3 veins in the umbilical cord.

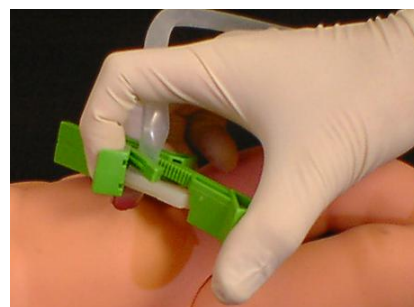
CORRECT-GRIP: BOTH HANDS



Grasp the umbilical cord using one hand and position **ClampCut®** around the umbilical cord using the other hand (app. 3 cm. from the infant's stomach).

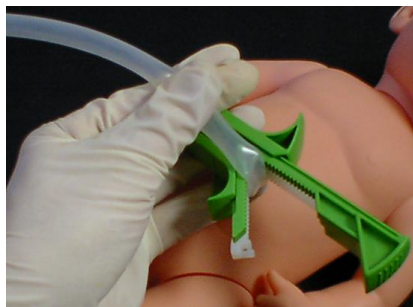


Making sure that the umbilical cord is placed correctly (see the arrow above), apply **ClampCut®** by closing the white clamp around the umbilical cord.



Cut the umbilical cord by pushing the slider into the housing. Left-handed users can use their left hand for this procedure.

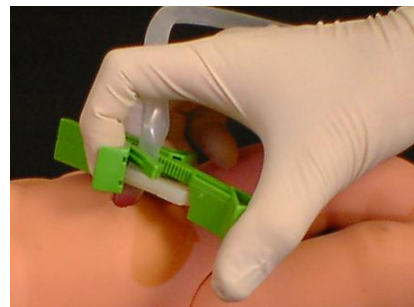
FATHER CUT



Positioning **ClampCut®** for the father.



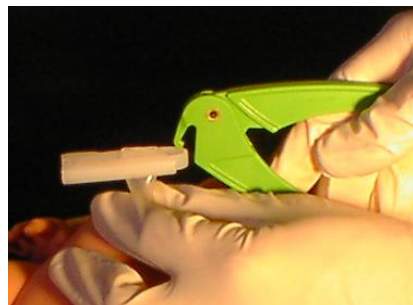
Making sure that the umbilical cord is placed correctly (see the arrow above), apply **ClampCut®** by closing the white clamp around the umbilical cord.



The father can cut the umbilical cord by simply pushing the slider into the housing, while the midwife holds **ClampCut®**.

4. Sometimes, the father wishes to cut the umbilical cord. If this is the case, simply use the correct-grip on **ClampCut®** and let the father push the slider into the housing, as shown in the pictures above.
5. To remove the clamp (when and if this is necessary depends on the hospital's procedure) use **ClampOff®** as demonstrated below.

REMOVAL OF THE CLAMP USING **CLAMPOFF®**



Hold the umbilical cord with one hand and **ClampOff®** with the other.



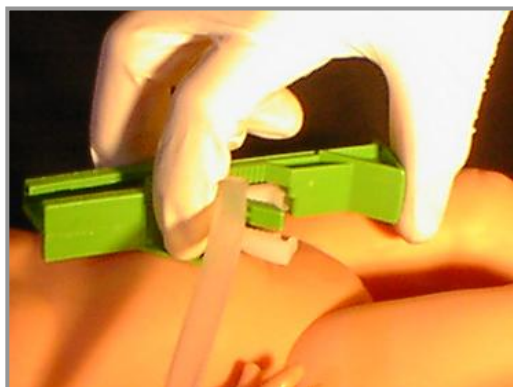
Place **ClampOff®** in the hole of the clamp



Cut the clamp by pressing the handles together. The clamp can now be opened.

Incorrect grip

There is one way in which **ClampCut®** can be used incorrectly – by using the correct-grip incorrectly. If the umbilical cord is *not* placed between the index and middle fingers, it will be pulled out of the clamp, when the slider is pushed into the housing, as demonstrated below.



Incorrect grip on **ClampCut®**. Notice the umbilical cord is on the wrong side of the index finger – it should have been between the index and middle fingers.



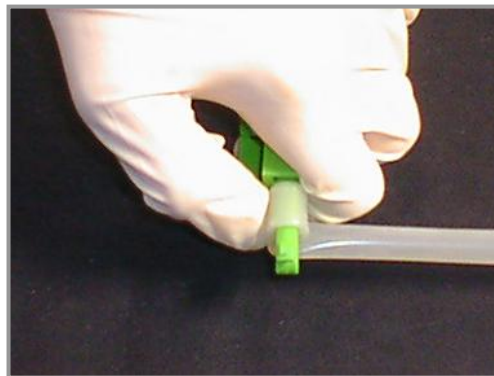
Result of using the incorrect grip - the umbilical cord blocks the closure of the clamp.

Evacuating the placenta

ClampCut® can be used for evacuation of the placenta and thereby save the use of an extra pair of forceps – this is shown below.



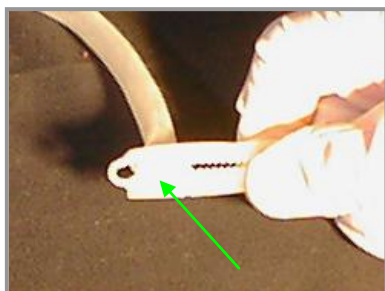
The umbilical cord is wound around the slider.



The slider and housing can then be used to pull when the placenta is being evacuated.

Frequently Asked Questions

This is a list of frequently asked questions – and their corresponding answers.



Checking the 3 vessels



The father can cut the umbilical cord by pushing the slider, while the midwife holds the housing.



ClampOff®

- **Can I still control the 3 vessels in the umbilical cord?** Yes, when the clamp is applied, it is easy to count the veins in the umbilical cord.
- **Can I take blood samples from the placenta?** Yes, the placenta side of **ClampCut®** can be opened and closed as needed.
- **Can I use **ClampCut®** if I'm lefthanded?** Yes, **ClampCut®** can be used with both hands - remember to show that in the demonstration.
- **When can the clamp be removed?** After 12-14 hours, it is safe to remove the clamp, but depending on the preferences of the hospital staff, the clamp can stay on the umbilical cord indefinitely or be removed with **ClampOff®**.
- **Can **ClampCut®** be used more than once?** No, **ClampCut®** is a disposable product.
- **How should I apply **ClampCut®**?** The white clamp must always face the infant's stomach.
- **Can the proud father still cut the umbilical cord?** Yes, if the obstetrician and/or midwife holds the device as shown in figure the father can cut the cord by simply sliding **ClampCut®**.
- **What if the umbilical cord is too big?** **ClampCut®** has been designed to fit *all* sizes and types of umbilical cords.
- **How close to the infant should I apply **ClampCut®**?** The recommended distance from the infant's stomach is 3-5 cm.
- **What if the umbilical cord is covered with gel?** **ClampCut®** should not be placed over the gel. Instead, place **ClampCut®** further away from the infant's stomach.
- **How far away from the infant can I apply **ClampCut®**?** Although the recommended distance is 3-5 cm, it can easily be applied 5-10 cm (or more) from the infant's stomach.
- **What if I want to remove the clamp?** The clamp can easily be removed using **ClampOff®** - a specially designed clamp remover (also sold by Price Invena). Notice that other Clamp removers cannot be used to remove the clamp, but **ClampOff®** is capable of removing existing clamps on the market.



ClampCut's® packaging with the yellow label, indicating that it is a sterilized product

- **Is **ClampCut®** packed in a sterile packaging?**
Yes, ClampCut® is sterilized using ethylene-oxide (ETO).
- **Does **ClampCut®** contain latex or PVC?** No, ClampCut® only consists of environmentally friendly materials such as nylon 6.6 and stainless steel. When the product is destructed the material will turn into water vapour.
- **How does the clamp differ from what I use now?** The actual clamp is virtually the same as the existing clamps on the market, which have been on the market for more than 30 years.
- **Can I still use **ClampCut®** during a Caesarian section?** Yes, ClampCut® is particularly advantageous during a Caesarian section, because it can be applied in less than 2 seconds.
- **Can I use **ClampCut®** when the child is born with the umbilical cord around its neck?** Yes, as shown in the figure to the left, using **ClampCut®** is a quick way to remove the umbilical cord from the child's neck.
- **There is already a lot of blood when a child is born. What difference can a little blood from the umbilical cord do?** The blood that is normally present during a delivery, that is coming from the vagina and which flows vertically in a controlled manner. Cutting the umbilical cord can be compared to cutting a pressurized garden tube – the blood can splash in all directions in an uncontrolled manner. **ClampCut®** prevents this from happening.
- **What if the pouch breach?** **ClampCut®** will not be sterile.
- **How many times can **ClampCut®** be used?**
ClampCut® can only be used once time.
ClampCut® is a disposable single used product.

If you have a question which is not on the list, please ask your local Price Invena sales representative or send an e-mail to info@priceinvena.dk.

Advantages using **ClampCut®**

Compared to the competing products, **ClampCut®** has many advantages – among these are:

ClampCut® was tested at Rigshospitalet in Copenhagen, Denmark and the results were published in an article in Acta Obstetricia:
- 0% blood splashing
- 0% repositioning of clamp
- 0% alternative method necessary.

- When **ClampCut®** is used correctly the risk of blood splashing is eliminated.
- Each device is assembled and tested 100% before it is packaged and sterilized – no risk of faulty devices.
- Clinically proven that there is a 0% risk of blood splashing – no risk of HIV and Hepatitis contamination.
- Disposable product – guaranteed sterility and razor-sharp blade – every time! No re-sterilizing necessary.
- Fast and efficient – application in less than 2 seconds in one easy movement.

Questions

If you have any questions or comments, please feel free to contact Price Invena at info@priceinvena.dk or your local Price Invena sales representative.